REMARKS

I. Amendments

Claims 3 and 26 have been canceled. Accordingly, the rejection of these claims under 35 U.S.C. § 102(b)/§103(a), is moot and should be withdrawn.

Claim 1 has been amended to incorporate the embodiment of canceled claim 3, and claim 24 has been amended to incorporate the embodiment of canceled claim 26. Support for the amendments to claims 1 and 24 is provided by the claims as originally filed. Claims 4, 10, 16-20, 23, 27, 33, and 37-41 have been amended to delete the dependency on canceled claims 3 and 26.

Upon entry of this Amendment, claims 1, 2, 4-20, 22-25, and 27-53 are pending. No new matter has been added by any of the amendments herein.

II. The claimed invention

The claimed invention is directed to a method for monitoring the formation of a coating on a particle. The method involves fluidizing the particle on an upwardly directed gas flow in order to place the particle at a given spatial location, forming the coating on the particle while at the given spatial location, and obtaining a spectroscopic measurement on the coating while the coating is being formed. In contrast to prior art methods, the claimed method permits extraction of information from several different depths of the coating, and measurement of the thickness of the coating, while the coating is being prepared. An apparatus for monitoring the formation of a coating on a particle is also claimed.

III. Rejections under 102(b) and/or 103(a)

Claims 1, 2, 7-9, 13-16, 20, 22-25, 27, 31, 32, 37, 41, 47, 48, and 53 are rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as allegedly being unpatentable over US 5,750,996 to Drennen III et al. ("Drennen"). The Examiner alleges that Drennen discloses the invention of these claims, or in the alternative, that the claimed invention is an obvious variation of Drennen. Applicants disagree that Drennen discloses or suggests the claimed invention.

The claimed invention is distinguishable over Drennen for at least the following reasons:

a) Drennen does not disclose or suggest positioning a single particle at a given spatial location by an upwardly directed gas flow prior to applying the coating;

b) Drennen does not disclose or suggest forming the coating on the particle while the particle is located at the given spatial location; and

c) Drennen does not disclose or suggest performing a spectrometric measurement on the coating ***while*** the coating is being applied to the single particle.

Each of these features of the claimed invention will be discussed in turn below.

A. Drennen does not disclose or suggest arranging a single particle at a given spatial location prior to coating.

In Fig. 2, Drennen shows a coating chamber 10 within which a plurality of articles 49 are carried upwards by a fan-generated air flow. The articles are coated by coating material 46 which emerges from coating nozzle 48. The nozzle 48 sprays the coating material in the direction generally shown by reference numeral 46 so as to coat the moving articles. The coated articles exit the coating chamber 10 in the direction of arrows C and D, that is, downwardly through annular passage 14 (col. 4, lines 36-43).

Contrary to the claimed invention, the articles coated by Drennen's apparatus are ***not*** positioned at a given position by an upwardly directed gas flow to be sprayed by the coating material. Rather, Drennen discloses that the articles are coated as they are pushed upward and move through the coating chamber 10. In other words, the articles to be coated travel generally through the sprayed coating material. There is not a given spatial position at which the articles are coated.

In accordance with the claimed invention, a single particle to be coated is placed *and maintained* at a given spatial position by fluidizing the particle by means of an upwardly directed gas flow. Specifically, the claimed invention comprises a control system to position the particle to be coated at a given spatial position. The control system includes a position sensor, such as an array detector, which feeds a signal to a main control unit and which adjusts the fluidized gas flow in the coating chamber of the invention. The control system is capable of maintaining the

particle at the given position in the coating chamber. This particle position can be spatially fixed or changed in a controlled manner (page 7, lines 26-33).

Drennen neither discloses nor suggests the above-recited feature of the claimed invention, i.e., arranging a single particle prior to coating at a given spatial location by means of an upwardly directed gas flow.

There is also no disclosure or suggestion that Drennen's apparatus comprises a means for arranging and maintaining the *single* particle at a given spatial location for coating. Rather, in accordance with Drennen, the articles merely move through the inner chamber of the coating apparatus without being positioned at a given spatial position prior to coating. Therefore, this feature of the claimed invention is not disclosed or suggested by Drennen.

B. Drennen does not disclose or suggest forming the coating on the single particle while the particle is held at the given spatial location.

Drennen discloses that articles 49 are carried upwards within the inner coating chamber 10 by the air flow, and are coated by coating material 46 which emerges from nozzle 48. The nozzle 48 sprays the coating material 46 in the interior of the coating chamber (Fig. 2). As the articles are in motion and travel past the nozzle, they become coated by the sprayed coating material. There is no particular spatial position at which the articles 49 become coated by the coating nozzle 48. Rather, the articles are coated as they generally move up and through the sprayed coating material.

In contrast to Drennen, the claimed invention is directed to a method and apparatus wherein a particle is coated while it is located at the given spatial location. As the particle is held at the given position by the position sensor 9, it is coated with the coating material. The coating material can be applied by a fluid supply unit such as a coating liquid dispenser which is adapted to sequentially generate droplets of the coating liquid. The generated droplets are injected into the gas flow, impinge upon the particles, and form a coating on the particles (page 8, lines 6-11).

The feature of the claimed invention, wherein the coating is formed while the particle is held at the given spatial location, is neither disclosed nor suggested by Drennen.

C. Drennen does not disclose or suggest obtaining a spectrometric measurement on the coating *while* the coating is being formed.

Drennen discloses that a spectrometric measurement of the articles is performed *after* they have been coated. The probe 20 receives a coated article 27 *after* the article has passed up through the coating spray 46. Articles which are coated by the material delivered through nozzle 48 travel upwardly and through the coating chamber 10, and then downwardly through annular passage 14 (Figs. 1 and 2; and col. 3, line 63 - col. 4, line 2). In other words, to reach the probe 20, a coated article must first move up through the coating chamber 10, and then through the outer annular passage 14 surrounding the coating chamber 10. Articles in the annular passage 14, and especially in the recess 34 of the probe 20 located in the annular passage 14, are no longer in the vicinity of the coating spray 46. As illustrated in Figs. 1 and 2, articles which are located within the annular passage 14, and especially in the spectroscopic probe 20 for analysis, are isolated from the coating process. Therefore, the articles are not and cannot be coated while the spectroscopic measurement is being obtained. The spectroscopic measurement is and can only be obtained after the article has exited the coating chamber 10 and is no longer being coated.

In contrast to Drennen, a spectroscopic measurement in accordance with the claimed invention is obtained *while the coating is being applied to the particle*. In one embodiment, the spectroscopic measurement is obtained by near infrared spectrometry (NIRS), and the resulting measurement data are represented in a sample vector (page 8, lines 24-29). The claimed invention allows for continuous and non-invasive monitoring of one or more principal parameters related to the coating, such as coating thickness and coating growth rate, *during the coating process on a particle* (page 4, lines 22-26). The particle is not removed from the given spatial position in order to obtain the spectroscopic measurement. By effecting a coating process at controlled conditions and continuously performing the spectroscopic measurement on a single particle *while the coating is being applied*, global process parameters can be obtained. Advantageously, these process parameters can then be applied during full-scale production of dosage units such as tablets or capsules (page 5, lines 5-13).

The above-recited feature of the claimed invention, wherein the spectroscopic measurement is obtained while the particle is being coated, is neither disclosed nor suggested by

Drennen. There is no appreciation by Drennen that coating formation can be monitored while the coating is being applied, and there is no suggestion that the disclosed apparatus comprises means for concurrently coating and spectroscopically analyzing the coating on a single particle.

D. Summary

In summary, Drennen neither discloses nor suggests the above-recited features of the invention of claims 1 and 24. With regard to claim 1, Drennen does not disclose or suggest the following steps of Applicants' process for monitoring the formation of a coating on a single particle:

a) arranging a single particle at a given spatial location comprising: fluidizing the particle on an upwardly directed gas flow;

b) forming the coating on the particle at the given spatial location; and

c) performing a spectrometric measurement on the coating while the coating is being formed.

With regard to claim 24, Drennen does not disclose or suggest the following features of Applicants' apparatus for monitoring the formation of a coating on a single particle:

a) means for arranging a single particle comprising a flow unit which generates a fluidizing gas flow upon which the particle is fluidized;

b) a fluid supply unit which supplies a coating fluid to the particle while the particle is located at a given spatial position; and

c) a measurement unit which performs a spectrometric measurement on the coating while the coating is being formed.

Accordingly, the inventions of independent claims 1 and 24 are clearly not disclosed by Drennen and are distinguishable over Drennen. The inventions of claims 2, 7-9, 13-16, 20, 22, 23, 31, 32, 37, 41, 48, and 53, which are directly or indirectly dependent upon claims 1 and 24, are novel and not obvious for the same reasons that claims 1 and 24 are novel and inventive. Withdrawal of the rejection of claims 1, 2, 7-9, 13-16, 20, 22, 23-26, 31, 32, 37, 41, 48, and 53 under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. § 103(a), is respectfully requested.

IV. Rejections under 35 U.S.C. § 103(a)

Claims 4-6, 28-30, 35, and 36 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Drennen in view of US 4,125,391 to Van Laethem ("Van Laethem").

Claims 10, 33, 42-44, and 50 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Drennen in view of US 5,520,681 to Cody ("Cody").

Claims 11, 17, 38, and 45 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Drennen in view of US 6,038,525 to Maguire et al. ("Maguire").

Claims 12, 34, 46, and 52 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Drennen in view of Van Laethem and in further view of US 6,248,363 to Patel et al. ("Patel").

Claims 18 and 39 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Drennen in view of US 5,091,278 to Teuscher et al. ("Teuscher").

Claims 19 and 40 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Drennen in view of US 5,420,681 to Woodruff ("Woodruff").

Claims 49 and 51 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Drennen in view of Laethem and in further view of Cody.

The Examiner alleges that Drennen lacks certain elements of the inventions of claims 4-6, 10-12, 18, 19, 28-30, 33-40, 42-46, and 49-52, and therefore relies upon the above-cited combinations of Van Laethem, Cody, Maguire, Patel, Teuscher, and Woodruff for alleged disclosures of these deficiencies. The Examiner alleges that it would have been obvious to combine Drennen with the respective secondary references to obtain the inventions of claims 4-6, 10-12, 18, 19, 28-30, 33-40, 42-46, and 49-52.

Applicants submit that their comments in Section III above, regarding the rejection under 35 U.S.C. §102(b) / §103(a) in view of Drennen, are applicable and therefore responsive to the rejections of claims 4-6, 10-12, 18, 19, 28-30, 33-40, 42-46, and 49-52 under §103(a) in further view of Van Laethem, Cody, Maguire, Patel, Teuscher, and/or Woodruff. In brief, the claimed invention is not anticipated or disclosed by Drennen, and Van Laethem, Cody, Maguire, Patel, Teuscher, and Woodruff does not overcome the deficiencies of Drennen to suggest the claimed invention. Furthermore, the cited combinations of documents do not suggest or yield the claimed invention.

Accordingly, withdrawal of the rejections of claims 4-6, 10-12, 18, 19, 28-30, 33-40, 42-46, and 49-52 under 35 U.S.C. § 103(a) is requested.

CONCLUSION

Upon entry of this Amendment, claims 1, 2, 4-20, 22-25 and 27-53 are pending. Applicants submit that the pending claims are in condition for allowance, which action is urgently requested.

Authorization is hereby given to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

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Respectfully submitted,

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